

ATTACHMENT

*THE eCTD DOCUMENT INFORMATION BACKBONE FILES SPECIFICATION
FOR MODULE 1*

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The eCTD Document Information Backbone Files Specification for Module 1

This discusses issues related to the electronic common technical document (eCTD) specification for the creation of the eCTD document information backbone file (eCTD backbone file) for module 1 for electronic submission of applications for human pharmaceutical products and related submissions to the FDA.

The module 1 eCTD backbone file includes document information for each module 1 document and a hyperlink to the document. This information and hyperlink are provided within an XML leaf element. The leaf element is fully described in *Guidance to Industry: M2 eCTD: Electronic Common Technical Document Specification*. The leaf elements in the module 1 eCTD backbone file are organized using XML heading elements. The XML heading elements are named and organized according to the subject matter of the documents. See *Providing Regulatory Submissions in Electronic Format — Human Pharmaceutical Product Applications and Related Submissions* for the headings used to organize documents in Module 1.

The module 1 eCTD backbone file also includes specific information about the application. The information is available as element content and as attribute values so that it can be read by computer systems used in FDA Automated Document Management Systems (ADMS).

Module 1 includes a wide range of applications and related submission types. A single submission will not use all the headings provided in module 1. You should not include XML heading elements that are not needed to organize the documents in your submission to the Agency.

The remainder of this document provides details on the creation of the module 1 eCTD backbone file.

I. START OF THE MODULE 1 ECTD BACKBONE FILE

You should name the module 1 eCTD backbone file *us-regional.xml* and place it in the *us* folder that is in the folder named *m1*.

The first elements of the module 1 eCTD backbone file are always the same. They contain machine-readable information about the following:

- Version of XML being used
- Type of characters that are allowed in the file
- Location of the standards that control the organization of the file

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You should create these elements and place them at the top of each module 1 eCTD backbone file. A sample of the common elements is provided:

```
<?xml version="1.0" encoding="UTF-8"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "util/us-regional.xml">
  < fda-regional:fda-regional
    xmlns:ectd="http://www.ich.org/ectd"
    xmlns:xlink="hyyp://www.w3c.org/1999/xlink">
```

You should place all the content of the module 1 eCTD backbone file after these lines and before the "end tag" for the file. The end tag is always the same. A sample of the end tag is provided:

```
</fda-regional:fda-regional>
```

II. INDIVIDUAL DOCUMENT INFORMATION; "LEAF" ELEMENT

Information for an individual document is contained in the leaf element, its attributes and its "title" element. The leaf element is used repeatedly throughout the eCTD backbone files to provide individual information for each document being submitted. Detailed descriptions of each part of the leaf element and how to use them are found in the document: *Guidance to Industry: M2 eCTD: Electronic Common Technical Document Specification*.

III. XML ELEMENTS GENERAL DESCRIPTION

The module 1 eCTD backbone file is divided into two parts. The first part contains information that can be read by machine directly for use by ADMS. This part is organized under the XML element named *admin*. The elements contained in this section are called the "information" elements. The second part contains leaf elements and heading elements to organize other electronic documents submitted as part of module 1. This part is organized under the XML element named *m1-regional*. The elements contained in this section are called "heading" elements.

Information about how to create an XML element can be found in the document named *Guidance to Industry: M2 eCTD: Electronic Common Technical Document Specification*.

A. Admin Element

You should create the element, *admin*, contained in the *fda-regional:fda-regional* element¹. Create three XML heading elements contained in the element named *admin*. These three elements are named *applicant-info*, *product-description*, and *application-information*. These elements should be placed in the same order as they are listed above. The information contained in these heading elements is discussed in detail under its own section of this document.

¹ Both the start tag and the end tag should be placed in between the start and end tags of the *fda-regional:fda-regional* element.

1. Applicant-info *Element*

You should create the following two elements contained in the *applicant-info* element: *company-name*, and *date-of-submission*. These are discussed below:

a) *Company-name* Element

You should contain the sponsor's name in the *company-name* element. An example of the *company-name* element for the “VeryBest Drug Company” with its content is provided:

```
<company-name>VeryBest Drug Company</company-name>
```

You should provide this element with every submission.

b) *Date-of-submission* Element

You should create an element named *date*, contained in the *date-of-submission* element. You should place the date of submission in the *date* element. This is sometimes referred to as the "letter date" because it can be the same as the date on the cover letter. Provide an attribute for the *date* element named *format*. The format has a fixed value of "yyyymmdd" and indicates the content of the date element is the four-digit year followed by two-digit month followed by two-digit day.

An example of the *date-of-submission* element with its content is provided:

```
<date-of-submission>  
  <date format="yyyymmdd">20020208</date>  
</date-of-submission >
```

You should provide this element with every submission.

2. Product-description *Element*

You should create the following two elements contained in the *product-description* element: *application-number*, and *prod-name*. These are discussed below:

a) *Application-number* Element

You should contain the application number in the *application-number* element. You should provide only the digits for the application number without letters or dashes. An example of the *application-number* element for NDA 999-999 with its content is provided:

```
<application-number>999999</application-number >
```

You should provide this element with every sequence number submission to the application.

b) *Prod-name* Element

You should create *prod-name* elements to contain four different types of product name, all of which can occur in a single submission. Provide an attribute for the *prod-name* element named *type*. Indicate the *type* of product name you contained in the *prod-name* element by choosing one of the four allowed values. The table below lists the available product name types (*type* attribute values) with their meaning:

<i>type</i> Attribute and Value	Product Name Type
type="established"	Established name (e.g., proper name, USP/USAN)
type="proprietary"	Proprietary name (e.g., brand name, trade name)
type="chemical"	Chemical name. (spell Greek characters and don't use superscript or subscript)
type="code"	Internal code used by the application sponsor.

There is no limit to the number of *prod-name* elements. An example of *prod-name* elements with their *type* attribute values and content is provided:

```
<prod-name type="proprietary">Cure All</prod-name >
<prod-name type="established">Cures</prod-name >
<prod-name type="chemical">H2O</prod-name >
<prod-name type="code">alpha-8</prod-name >
<prod-name type="code">beta-3</prod-name >
```

You should provide at least one *prod-name* element with each sequence numbered submission to the application.

3. Application-information *Element*

You should create an element named *application-information* contained in the *admin* element. The *application-information* element contains the *submission* element. You should provide an attribute for the *application-information* element named *application-type*. Indicate the type of application for this submission in the *application-type* element by choosing one of the types allowed. The table below lists the available application types (*application-type* attribute values) with their meaning:

application-type Attribute and Value	Application Type
application-type="nda"	New Drug Application
application-type="anda"	Abbreviated New Drug Application
application-type="bla"	Biologics License Application
application-type="ind"	Investigational new drug application.
application-type="master file"	Master file

a) *Submission* Element

You should create an element named *submission* contained in the *application-information* element. You should contain the following elements in the *submission* element: *sequence-number*, and *related-sequence-number* (if needed). You should provide three attributes for the *submission* element, *submission-type*, *supplement-type* and *other-type*. You should contain the type of submission in the *submission-type* attribute value. The table below lists the available submission types (*submission-type* attribute values) with their meanings:

Attribute Name and Value	Meaning
submission-type="original-application"	A complete new application that has never before been submitted
"amendment"	All submissions to pending original submission or pending supplements to approved applications including responses to information request letters
"resubmission"	A complete response to an action letter, or submission of an application that has been the subject of a withdrawal or a refusal to file
"presubmission"	Information submitted prior to the submission of a complete new application
"annual-report"	Annual Reports to applications
"establishment-description-supplement"	Supplements to the information contained in the establishment description section for biological products
"efficacy-supplement"	Submissions for such changes as a new indication or dosage regimen for an approved product, a comparative efficacy claim naming another product, or a significant alteration in the patient population; e.g., prescription to Over-The-Counter switch
"labeling-supplement"	All label change supplements required under 21 CFR 314.70 and 21 CFR 601.12 that do not qualify as efficacy supplements;
"chemistry-manufacturing-controls-supplement"	Manufacturing and Controls Supplement manufacturing change supplement submissions as provided in 21 CFR 314.70, 21 CFR 314.71, 21 CFR 314.72 and 21 CFR 601.12
"other"	Not among those listed above

(1) *Sequence-number* Element

You should include the sequence number of the submission in the *sequence-number* element. The sequence number should be exactly 4 digits with no spaces between them. You should

provide a *sequence-number* element with every submission. An example of the original application sequence number element with its content is provided:

```
<sequence-number>0000</sequence-number>
```

(2) *Related-sequence-number* Element

When providing an amendment to an earlier submission, you should include the sequence number of the earlier submission in the *related-sequence-number* element. The sequence number should be exactly 4 digits with no spaces between them. If this submission is related to more than one previous submission, you should provide each previous submission's sequence number in a separate *related-sequence-number* element. There is no limit to the number of *related-sequence-number* elements. The following is an example of the related sequence number. An application has the following submissions:

- 0000 - Original application
- 0001 - an amendment to original application
- 0002 - an amendment to original application
- 0003 - a chemistry, manufacturing and control supplement
- 0004 - an amendment to original application
- 0005 - an amendment to the supplement
- 0006 - an amendment to the supplement
- 0007 - an amendment that relates to both the original and supplement

A non-XML representation would relate this as:

Sequence-number	Related-sequence-number***
0000	
0001	0000
0002	0000
0003	
0004	0000
0005	0003
0006	0000
0007	0000 0003

Example XML coding for the original application or original supplement would look like (example shown is for an original supplement):

```
<submission submission-type="chemistry-manufacturing-controls-supplement ">  
  <sequence-number>0003</sequence-number>  
</submission>
```

Example XML coding for a *submission* element of an amendment that would apply to two or more original submissions, such as sequence number 0007 above, would look like:

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```
<submission submission-type="chemistry-manufacturing-controls-supplement">
  <sequence-number>0006</sequence-number>
  <related-sequence-number>0000</related-sequence-number>
  <related-sequence-number>0003</related-sequence-number>
</submission>
```

Example XML coding for an amendment to an original application or original supplement (example shown is for an amendment to the original application):

```
<submission submission-type="amendment">
  <sequence-number>0002</sequence-number>
  <related-sequence-number>0000</related-sequence-number>
</submission>
```

B. *M1-regional* element

Hyperlinks to the Documents submitted for Module 1 are provided in "leaf" elements described in *Guidance to Industry: M2 eCTD: Electronic Common Technical Document Specification*. Leaf elements in the module 1 eCTD backbone file are organized using 14 XML heading elements. These are further divided into subheading elements.

The table below provides the module 1 eCTD backbone file heading and subheading elements with the corresponding "leaf"² elements you should contain in them. No additional subheadings elements should be used. Both the "start tag"³ and "end tag"⁴ for each XML element is provided. If there are one or more subheadings for the heading, the corresponding element's end tag will occur on the table row below the last relevant subheading. Notice that the table starts with the *m1-regional* element start tag and ends with its end tag. Although there is one leaf element for each document under a subheading, leaf elements are not shown on this table to keep it clearer. Leaf elements should only occur as content for the subheading element that is at the lowest possible level in the hierarchy. These subheading elements may contain any number of leaf elements. If you submit no document heading or subheading, you should omit the corresponding elements.

Document Leaf	XML Heading and Subheading Elements
	<m1-regional>
1. Forms Choose one of the following elements to contain your form's leaf element.	<m1-1-forms>
a) Investigational New Drug (IND)	<m1-1-1-fda-form-1571> </m1-1-1-fda-form-1571>

² The leaf element is described in the appendix for ICH modules 2 through 5.

³ The start tag is described in the appendix for ICH modules 2 through 5.

⁴ The end tag is described in the appendix for ICH modules 2 through 5.

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Document Leaf	XML Heading and Subheading Elements
b) New Drug Application (NDA) or New Biologic Application (BLA)	<m1-1-2-fda-form-356h> </m1-1-2-fda-form-356h>
c) User Fee Cover Sheet	<m1-1-3-fda-form-3397> </m1-1-3-fda-form-3397>
d) Annual Report Transmittal	<m1-1-4-fda-form-2252> </m1-1-4-fda-form-2252>
e) Advertising and Promotional Labeling	<m1-1-5-fda-form-2253> </m1-1-5-fda-form-2253>
f) Transmittal of Labels and Circulars	<m1-1-6-fda-form-2567> </m1-1-6-fda-form-2567>
End of Forms	</m1-1-forms>
2. Cover Letters	<m1-2-cover-letters> </m1-2-cover-letters>
3. Administrative Information	<m1-3-administrative-information>
a) Applicant Information	<m1-3-1-applicant-information>
(1) Change of Address	<m1-3-1-1-cofa-con> </m1-3-1-1-cofa-con>
(2) Change of Agent	<m1-3-1-2-change-contact-agent> </m1-3-1-2-change-contact-agent>
(3) Sponsor Change	<m1-3-1-3-change-sponsor> </m1-3-1-3-change-sponsor>
(4) Obligation Transfer	<m1-3-1-4-transfer-obligation> </m1-3-1-4-transfer-obligation>
(5) Ownership Change	<m1-3-1-5-change-application-ownership> </m1-3-1-5-change-application-ownership>
End Applicant Information	</m1-3-1-applicant-information>
b) Field Copy Certification	<m1-3-2-field-copy-certification> </m1-3-2-field-copy-certification>
c) Debarment Certification	<m1-3-3-debarment-certification> </m1-3-3-debarment-certification>
d) Financial Disclosure	<m1-3-4-financial-certification-disclosure> </m1-3-4-financial-certification-disclosure>
e) Patent Exclusivity	<m1-3-5-patent-exclusivity>
(1) Patent Information	<m1-3-5-1-patent-information> </m1-3-5-1-patent-information>

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Document Leaf	XML Heading and Subheading Elements
(2) Patent Certification	<m1-3-5-2-patent-certification> </m1-3-5-2-patent-certification>
(3) Exclusivity Request	<m1-3-5-3-exclusivity-request> </m1-3-5-3-exclusivity-request>
End of Patent Exclusivity	</m1-3-5-patent-exclusivity>
End of Administrative Information	</m1-3-administrative-information>
4. Reference Section	<m1-4-references>
a) Letter of Authorization	<m1-4-1-letter-authorization> </m1-4-1-letter-authorization>
b) Statement of Right to Reference	<m1-4-2-statement-right-reference> </m1-4-2-statement-right-reference>
c) List of Authorized to Persons to Incorporate by Reference	<m1-4-3-list-authorized-persons-incorporate-reference> </m1-4-3-list-authorized-persons-incorporate-reference>
d) Cross Reference to Other Applications	<m1-4-4-cross-reference-other-applications> </m1-4-4-cross-reference-other-applications>
End References	</m1-4-references>
5. Application Status Documentation	<m1-5-application-status>
a) Withdrawal Request	<m1-5-1-withdrawal-request> </m1-5-1-withdrawal-request>
b) Inactivation Request	<m1-5-2-inactivation-request> </m1-5-2-inactivation-request>
c) Reactivation Request	<m1-5-3-reactivation-request> </m1-5-3-reactivation-request>
d) Reinstatement Request	<m1-5-4-reinstatement-request> </m1-5-4-reinstatement-request>
e) Withdrawal of Unapproved NDA	<m1-5-5-withdrawal-unapproved-nda> </m1-5-5-withdrawal-unapproved-nda>
f) Withdrawal of Listed Drug	<m1-5-6-withdrawal-of-listed-drug> </m1-5-6-withdrawal-of-listed-drug>
g) Request for Withdrawal of Application Approval	<m1-5-7-request-withdrawal-application-approval> </m1-5-7-request-withdrawal-application-approval>
End Application Status	</m1-5-application-status>
6. Meetings	<m1-6-meetings>
a) Meeting Request	<m1-6-1-meeting-request> </m1-6-1-meeting-request>

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Document Leaf	XML Heading and Subheading Elements
b) Meeting Background Materials	<m1-6-2-meeting-background-materials> </m1-6-2-meeting-background-materials>
c) Correspondence Regarding Meetings	<m1-6-3-correspondence-regarding-meetings> </m1-6-3-correspondence-regarding-meetings>
End Meetings	</m1-6-meetings>
7. Fast Track	<m1-7-fast-track>
a) Fast Track Designation Request	<m1-7-1-fast-track-designation-request> </m1-7-1-fast-track-designation-request>
b) Fast Track Designation Withdrawal Request	<m1-7-2-fast-track-designation-withdrawal-request> </m1-7-2-fast-track-designation-withdrawal-request>
c) Rolling Review Request	<m1-7-3-rolling-review-request> </m1-7-3-rolling-review-request>
End Fast Track	</m1-7-fast-track>
8. Special Protocol Assessment Request	<m1-8-special-protocol-assessment-request>
a) Clinical Study	<m1-8-1-clinical-study> <m1-8-1-clinical-study>
b) Carcinogenicity Study	<m1-8-2-carcinogenicity-study> <m1-8-2-carcinogenicity-study>
c) Stability Study	<m1-8-3-stability-study> <m1-8-3-stability-study>
End Special Protocol	</m1-8-special-protocol-assessment-request>
9. Pediatric Administrative Information	<m1-9-pediatric-administrative-information>
a) Request for Waiver of Pediatric Studies	<m1-9-1-request-waiver-pediatric-studies> </m1-9-1-request-waiver-pediatric-studies>
b) Request for Deferral of Pediatric Studies	<m1-9-2-request-deferral-pediatric-studies> </m1-9-2-request-deferral-pediatric-studies>

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Document Leaf	XML Heading and Subheading Elements
c) Request for Pediatric Exclusivity Determination	<m1-9-3-request-pediatric-exclusivity-determination> </m1-9-3-request-pediatric-exclusivity-determination>
d) Proposed Pediatric Study Request and amendments	<m1-9-4-proposed-pediatric-study-request-amendments> </m1-9-4-proposed-pediatric-study-request-amendments>
e) Proposal for Written Agreement	<m1-9-5-proposal-written-agreement> </m1-9-5-proposal-written-agreement>
f) Other Correspondence Regarding Pediatric Exclusivity or Study Plans	<m1-9-6-other-correspondence-regarding-pediatric-exclusivity-study-plans> </m1-9-6-other-correspondence-regarding-pediatric-exclusivity-study-plans>
End Pediatric	</m1-9-pediatric-administrative-information>
10. Dispute Resolution	<m1-10-dispute-resolution>
a) Request for Dispute Resolution	<m1-10-1-request-for-dispute-resolution> </m1-10-1-request-for-dispute-resolution>
b) Correspondence Related to Dispute Resolution	<m1-10-2-correspondence-related-to-dispute-resolution> </m1-10-2-correspondence-related-to-dispute-resolution>
End Dispute Resolution	</m1-10-dispute-resolution>
11. Information Not Covered Under Modules 2 to 5	<m1-11-information-amendment>
a) Quality Information Amendment	<m1-11-1-quality-information-amendment> </m1-11-1-quality-information-amendment>
b) Safety Information Amendment	<m1-11-2-safety-information-amendment> </m1-11-2-safety-information-amendment>
c) Efficacy Information Amendment	<m1-11-3-efficacy-information-amendment> </m1-11-3-efficacy-information-amendment>

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Document Leaf	XML Heading and Subheading Elements
d) Multiple Module Information Amendments	<m1-11-4-multiple-module-information-amendments> </m1-11-4-multiple-module-information-amendments>
End Modules	</m1-11-information-amendment>
12. Other Correspondence	<m1-12-other-correspondence>
a) Pre IND Correspondence	<m1-12-1-pre-ind-correspondence> </m1-12-1-pre-ind-correspondence>
b) Request to Charge	<m1-12-2-request-charge> </m1-12-2-request-charge>
c) Notification of Charging Under Treatment IND	<m1-12-3-notification-charging-under-treatment-ind> </m1-12-3-notification-charging-under-treatment-ind>
d) Request for Comments and Advice on an IND	<m1-12-4-request-comments-advice-ind> </m1-12-4-request-comments-advice-ind>
e) Request for Waiver	<m1-12-5-request-waiver> </m1-12-5-request-waiver>
f) Exemption from Informed Consent for Emergency Research	<m1-12-6-exemption-informed-consent-emergency-research> </m1-12-6-exemption-informed-consent-emergency-research>
g) Public Disclosure Statement for Emergency Care Research	<m1-12-7-public-disclosure-statement-emergency-care-research> </m1-12-7-public-disclosure-statement-emergency-care-research>
h) Correspondence Regarding Emergency Care Research	<m1-12-8-correspondence-regarding-emergency-care-research> </m1-12-8-correspondence-regarding-emergency-care-research>
i) Notification of Discontinuation of Clinical Trial	<m1-12-9-notification-discontinuation-clinical-trial> </m1-12-9-notification-discontinuation-clinical-trial>
j) Generic Drug Enforcement Act Statement	<m1-12-10-generic-drug-enforcement-act-statement> </m1-12-10-generic-drug-enforcement-act-statement>

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Document Leaf	XML Heading and Subheading Elements
k) Basis for Submission Statement	<m1-12-11-basis-submission-statement> </m1-12-11-basis-submission-statement>
l) Comparison of Generic Drug and Reference Listed Drug	<m1-12-12-comparison-generic-drug-reference-listed-drug> </m1-12-12-comparison-generic-drug-reference-listed-drug>
m) Request for Waiver For In Vivo Studies	<m1-12-13-request-waiver-in-vivo-studies> </m1-12-13-request-waiver-in-vivo-studies>
n) Environmental Analysis	<m1-12-14-environmental-analysis> </m1-12-14-environmental-analysis>
o) Request for Waiver of In Vivo Bioavailability Studies	<m1-12-15-request-waiver-in-vivo-bioavailability-studies> </m1-12-15-request-waiver-in-vivo-bioavailability-studies>
p) Field Alert Reports	<m1-12-16-field-alert-reports> </m1-12-16-field-alert-reports>
End of correspondence	</m1-12-other-correspondence>
13. Annual Report	<m1-13-annual-report>
a) Summary for Nonclinical Studies	<m1-13-1-summary-nonclinical-studies> </m1-13-1-summary-nonclinical-studies>
b) Summary for Clinical Pharmacology Information	<m1-13-2-summary-clinical-pharmacology-information> </m1-13-2-summary-clinical-pharmacology-information>
c) Summary of Safety Information	<m1-13-3-summary-safety-information> </m1-13-3-summary-safety-information>
d) Summary of Labeling Changes	<m1-13-4-summary-labeling-changes> </m1-13-4-summary-labeling-changes>
e) Summary of manufacturing changes	<m1-13-5-summary-of-manufacturing-changes> </m1-13-5-summary-of-manufacturing-changes>

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Document Leaf	XML Heading and Subheading Elements
f) Summary of microbiological changes	<m1-13-6-summary-of-microbiological-changes> </m1-13-6-summary-of-microbiological-changes>
g) Summary of Other Significant New Information	<m1-13-7-summary-other-significant-new-information> </m1-13-7-summary-other-significant-new-information>
h) Individual Study Information	<m1-13-8-individual-study-information> </m1-13-8-individual-study-information>
i) General Investigational Plan	<m1-13-9-general-investigational-plan> </m1-13-9-general-investigational-plan>
j) Foreign Marketing History	<m1-13-10-foreign-marketing-history> </m1-13-10-foreign-marketing-history>
k) Distribution Data	<m1-13-11-distribution-data> </m1-13-11-distribution-data>
l) Status of Postmarketing Study Commitments	<m1-13-12-status-postmarketing-study-commitments> </m1-13-12-status-postmarketing-study-commitments>
m) Status of Other Postmarketing Studies	<m1-13-13-status-other-postmarketing-studies> </m1-13-13-status-other-postmarketing-studies>
n) Log of Outstanding Regulatory Business	<m1-13-14-log-outstanding-regulatory-business> </m1-13-14-log-outstanding-regulatory-business>
End Annual Report	</m1-13-annual-report>
14. Labeling	<m1-14-labeling>
a) Draft Labeling	<m1-14-1-draft-labeling> </m1-14-1-draft-labeling>
(1) Draft Carton and Container Labels	<m1-14-1-1-draft-carton-container-labels> </m1-14-1-1-draft-carton-container-labels>

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Document Leaf	XML Heading and Subheading Elements
(2) Annotated Draft Labeling Text	<m1-14-1-2-annotated-draft-labeling-text> </m1-14-1-2-annotated-draft-labeling-text>
(3) Draft Labeling Text	<m1-14-1-3-draft-labeling-text> </m1-14-1-3-draft-labeling-text>
(4) Label Comprehension Studies	<m1-14-1-4-label-comprehension-studies> </m1-14-1-4-label-comprehension-studies>
(5) Labeling History	<m1-14-1-5-labeling-history> </m1-14-1-5-labeling-history>
b) Final Labeling	<m1-14-2-final-labeling> </m1-14-2-final-labeling>
(1) Final Carton or Container Labels	<m1-14-2-1-final-carton-container-labels> </m1-14-2-1-final-carton-container-labels>
(2) Final Package Insert (package inserts, patient information, medication guides)	<m1-14-2-2-final-package-insert-package-inserts> </m1-14-2-2-final-package-insert-package-inserts>
(3) Final labeling Text	<m1-14-2-3-final-labeling-text> </m1-14-2-3-final-labeling-text>
c) Listed Drug Labeling	<m1-14-3-listed-drug-labeling> </m1-14-3-listed-drug-labeling>
(1) Annotated Comparison with Listed Drug	<m1-14-3-1-annotated-comparison-listed-drug> </m1-14-3-1-annotated-comparison-listed-drug>
(2) Approved Labeling Text for Listed Drug	<m1-14-3-2-approved-labeling-text-listed-drug> </m1-14-3-2-approved-labeling-text-listed-drug>
(3) Labeling Text for Reference Listed Drug	<m1-14-3-3-labeling-text-reference-listed-drug> </m1-14-3-3-labeling-text-reference-listed-drug>
d) Investigational Drug Labeling	<m1-14-4-investigational-drug-labeling> </m1-14-4-investigational-drug-labeling>

Document Leaf	XML Heading and Subheading Elements
(1) Investigational Brochure	<m1-14-4-1-investigational-brochure> </m1-14-4-1-investigational-brochure>
(2) Investigational Drug Labeling	<m1-14-4-2-investigational-drug-label> </m1-14-4-2-investigational-drug-label>
e) Foreign Labeling	<m1-14-5-foreign-labeling> </m1-14-5-foreign-labeling>
End Labeling	</m1-14-labeling>
15. Promotional Material	<m1-15-promotional-material> </m1-15-promotional-material>
16. Risk Management Plans	<m1-16-risk-management-plans> </m1-16-risk-management-plans>
End Regional Leafs	</m1-regional>

IV. MODULE 1 EXAMPLE TEMPLATE

This is an example of XML for module one. It contains every possible element and attribute, but no element content or attribute values. Some of the elements shown here would not occur together in an actual submission. For example, you need to choose one of the form elements, although they are all shown in this example. In addition, you should not provide empty "heading" elements or "leaf" elements in your submission. You should use only the heading and leaf elements you need to properly organize the documents in your submission. A single, empty leaf element is provided for each subheading in this example to indicate where leaf elements should be contained. You can contain as many leaf elements as you need where there are leaf elements in this example.

```
<?xml version="1.0" encoding="UTF-8"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "util/us-regional.xml">
< fda-regional:fda-regional
  xmlns:ectd="http://www.ich.org/ectd"
  xmlns:xlink="hyyp://www.w3c.org/1999/xlink">
  <admin>
  <applicant-info>
    <company-name> </company-name>
    <date-of-submission>
      <date format="yyyymmdd"></date>
    </date-of-submission>

    <product-description>
      <application-number></application-number >
      <prod-name type=""></prod-name >
```

```
</product-description>

<application-information
  application-type=" ">
  <submission
    submission-type=" "
    supplement-type=" "
    other-type=" ">
    <sequence-number></sequence-number>
    <related-sequence-number></related-sequence-number>
  </submission>
</application-information>
</admin>

<m1-regional>
<m1-1-forms>
  <m1-1-1-fda-form-1571>
</m1-1-1-fda-form-1571>
  <m1-1-2-fda-form-356h>
</m1-1-2-fda-form-356h>
  <m1-1-3-fda-form-3397>
</m1-1-3-fda-form-3397>
  <m1-1-4-fda-form-2252>
</m1-1-4-fda-form-2252>
  <m1-1-5-fda-form-2253>
</m1-1-5-fda-form-2253>
  <m1-1-6-fda-form-2567>
</m1-1-6-fda-form-2567>
</m1-1-forms>
<m1-2-cover-letters>
</m1-2-cover-letters>
<m1-3-administrative-information>
  <m1-3-1-applicant-information>
    <m1-3-1-1-cofa-con>
</m1-3-1-1-cofa-con>
    <m1-3-1-2-change-contact-agent>
</m1-3-1-2-change-contact-agent>
    <m1-3-1-3-change-sponsor>
</m1-3-1-3-change-sponsor>
    <m1-3-1-4-transfer-obligation>
</m1-3-1-4-transfer-obligation>
    <m1-3-1-5-change-application-ownership>
</m1-3-1-5-change-application-ownership>
  </m1-3-1-applicant-information>
  <m1-3-2-field-copy-certification>
</m1-3-2-field-copy-certification>
```

```
<m1-3-3-debarment-certification>
</m1-3-3-debarment-certification>
<m1-3-4-financial-certification-disclosure>
</m1-3-4-financial-certification-disclosure>
<m1-3-5-patent-exclusivity>
    <m1-3-5-1-patent-information>
    </m1-3-5-1-patent-information>
    <m1-3-5-2-patent-certification>
    </m1-3-5-2-patent-certification>
    <m1-3-5-3-exclusivity-request>
    </m1-3-5-3-exclusivity-request>
</m1-3-5-patent-exclusivity>
</m1-3-administrative-information>
<m1-4-references>
    <m1-4-1-letter-authorization>
    </m1-4-1-letter-authorization>
    <m1-4-2-statement-right-reference>
    </m1-4-2-statement-right-reference>
    <m1-4-3-list-authorized-persons-incorporate-reference>
    </m1-4-3-list-authorized-persons-incorporate-reference>
    <m1-4-4-cross-reference-other-applications>
    </m1-4-4-cross-reference-other-applications>
</m1-4-references>
<m1-5-application-status>
    <m1-5-1-withdrawal-request>
    </m1-5-1-withdrawal-request>
    <m1-5-2-inactivation-request>
    </m1-5-2-inactivation-request>
    <m1-5-3-reactivation-request>
    </m1-5-3-reactivation-request>
    <m1-5-4-reinstatement-request>
    </m1-5-4-reinstatement-request>
    <m1-5-5-withdrawal-unapproved-nda>
    </m1-5-5-withdrawal-unapproved-nda>
    <m1-5-6-withdrawal-of-listed-drug>
    </m1-5-6-withdrawal-of-listed-drug>
    <m1-5-7-request-withdrawal-application-approval>
    </m1-5-7-request-withdrawal-application-approval>
</m1-5-application-status>
<m1-6-meetings>
    <m1-6-1-meeting-request>
    </m1-6-1-meeting-request>
    <m1-6-2-meeting-background-materials>
    </m1-6-2-meeting-background-materials>
    <m1-6-3-correspondence-regarding-meetings>
```

```
</m1-6-3-correspondence-regarding-meetings>
</m1-6-meetings>
<m1-7-fast-track>
  <m1-7-1-fast-track-designation-request>
  </m1-7-1-fast-track-designation-request>
  <m1-7-2-fast-track-designation-withdrawal-request>
  </m1-7-2-fast-track-designation-withdrawal-request>
  <m1-7-3-rolling-review-request>
  </m1-7-3-rolling-review-request>
</m1-7-fast-track>
<m1-8-special-protocol-assessment-request>
  <m1-8-1-clinical-study>
  <m1-8-1-clinical-study>
  <m1-8-2-carcinogenicity-study>
  <m1-8-2-carcinogenicity-study>
  <m1-8-3-stability-study>
  <m1-8-3-stability-study>
</m1-8-special-protocol-assessment-request>
<m1-9-pediatric-administrative-information>
  <m1-9-1-request-waiver-pediatric-studies>
  </m1-9-1-request-waiver-pediatric-studies>
  <m1-9-2-request-deferral-pediatric-studies>
  </m1-9-2-request-deferral-pediatric-studies>
  <m1-9-3-request-pediatric-exclusivity-determination>
  </m1-9-3-request-pediatric-exclusivity-determination>
  <m1-9-4-proposed-pediatric-study-request-amendments>
  </m1-9-4-proposed-pediatric-study-request-amendments>
  <m1-9-5-proposal-written-agreement>
  </m1-9-5-proposal-written-agreement>
  <m1-9-6-other-correspondence-regarding-pediatric-exclusivity-study-
plans>
  </m1-9-6-other-correspondence-regarding-pediatric-exclusivity-study-
plans>
</m1-9-pediatric-administrative-information>
<m1-10-dispute-resolution>
  <m1-10-1-request-for-dispute-resolution>
  </m1-10-1-request-for-dispute-resolution>
  <m1-10-2-correspondence-related-to-dispute-resolution>
  </m1-10-2-correspondence-related-to-dispute-resolution>
</m1-10-dispute-resolution>
<m1-11-information-amendment>
  <m1-11-1-quality-information-amendment>
  </m1-11-1-quality-information-amendment>
  <m1-11-2-safety-information-amendment>
  </m1-11-2-safety-information-amendment>
  <m1-11-3-efficacy-information-amendment>
```

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</m1-11-3-efficacy-information-amendment>
<m1-11-4-multiple-module-information-amendments>
</m1-11-4-multiple-module-information-amendments>
</m1-11-information-amendment>
<m1-12-other-correspondence>
<m1-12-1-pre-ind-correspondence>
</m1-12-1-pre-ind-correspondence>
<m1-12-2-request-charge>
</m1-12-2-request-charge>
<m1-12-3-notification-charging-under-treatment-ind>
</m1-12-3-notification-charging-under-treatment-ind>
<m1-12-4-request-comments-advice-ind>
</m1-12-4-request-comments-advice-ind>
<m1-12-5-request-waiver>
</m1-12-5-request-waiver>
<m1-12-6-exemption-informed-consent-emergency-research>
</m1-12-6-exemption-informed-consent-emergency-research>
<m1-12-7-public-disclosure-statement-emergency-care-research>
</m1-12-7-public-disclosure-statement-emergency-care-research>
<m1-12-8-correspondence-regarding-emergency-care-research>
</m1-12-8-correspondence-regarding-emergency-care-research>
<m1-12-9-notification-discontinuation-clinical-trial>
</m1-12-9-notification-discontinuation-clinical-trial>
<m1-12-10-generic-drug-enforcement-act-statement>
</m1-12-10-generic-drug-enforcement-act-statement>
<m1-12-11-basis-submission-statement>
</m1-12-11-basis-submission-statement>
<m1-12-12-comparison-generic-drug-reference-listed-drug>
</m1-12-12-comparison-generic-drug-reference-listed-drug>
<m1-12-13-request-waiver-in-vivo-studies>
</m1-12-13-request-waiver-in-vivo-studies>
<m1-12-14-environmental-analysis>
</m1-12-14-environmental-analysis>
<m1-12-15-request-waiver-in-vivo-bioavailability-studies>
</m1-12-15-request-waiver-in-vivo-bioavailability-studies>
<m1-12-16-field-alert-reports>
</m1-12-16-field-alert-reports>
</m1-12-other-correspondence>
<m1-13-annual-report>
<m1-13-1-summary-nonclinical-studies>
</m1-13-1-summary-nonclinical-studies>
<m1-13-2-summary-clinical-pharmacology-information>
</m1-13-2-summary-clinical-pharmacology-information>
<m1-13-3-summary-safety-information>
</m1-13-3-summary-safety-information>
<m1-13-4-summary-labeling-changes>

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```
</m1-13-4-summary-labeling-changes>
<m1-13-5-summary-manufacturing-changes>
</m1-13-5-summary-of-manufacturing-changes>
<m1-13-6-summary-of-microbiological-changes>
</m1-13-6-summary-of-microbiological-changes>
<m1-13-7-summary-other-significant-new-information>
</m1-13-7-summary-other-significant-new-information>
<m1-13-8-individual-study-information>
</m1-13-8-individual-study-information>
<m1-13-9-general-investigational-plan>
</m1-13-9-general-investigational-plan>
<m1-13-10-foreign-marketing-history>
</m1-13-10-foreign-marketing-history>
<m1-13-11-distribution-data>
</m1-13-11-distribution-data>
<m1-13-12-status-postmarketing-study-commitments>
</m1-13-12-status-postmarketing-study-commitments>
<m1-13-13-status-other-postmarketing-studies>
</m1-13-13-status-other-postmarketing-studies>
<m1-13-14-log-outstanding-regulatory-business>
</m1-13-14-log-outstanding-regulatory-business>
</m1-13-annual-report>
<m1-14-labeling>
  <m1-14-1-draft-labeling>
    <m1-14-1-1-draft-carton-container-labels>
    </m1-14-1-1-draft-carton-container-labels>
    <m1-14-1-2-annotated-draft-labeling-text>
    </m1-14-1-2-annotated-draft-labeling-text>
    <m1-14-1-3-draft-labeling-text>
    </m1-14-1-3-draft-labeling-text>
    <m1-14-1-4-label-comprehension-studies>
    </m1-14-1-4-label-comprehension-studies>
    <m1-14-1-5-labeling-history>
    </m1-14-1-5-labeling-history>
  </m1-14-1-draft-labeling>
  <m1-14-2-final-labeling>
    <m1-14-2-1-final-carton-container-labels>
    </m1-14-2-1-final-carton-container-labels>
    <m1-14-2-2-final-package-insert-package-inserts>
    </m1-14-2-2-final-package-insert-package-inserts>
    <m1-14-2-3-final-labeling-text>
    </m1-14-2-3-final-labeling-text>
  </m1-14-2-final-labeling>
  <m1-14-3-listed-drug-labeling>
    <m1-14-3-1-annotated-comparison-listed-drug>
    </m1-14-3-1-annotated-comparison-listed-drug>
```

```
<m1-14-3-2-approved-labeling-text-listed-drug>
</m1-14-3-2-approved-labeling-text-listed-drug>
<m1-14-3-3-labeling-text-reference-listed-drug>
</m1-14-3-3-labeling-text-reference-listed-drug>
</m1-14-3-listed-drug-labeling>
<m1-14-4-investigational-drug-labeling>
  <m1-14-4-1-investigational-brochure>
  </m1-14-4-1-investigational-brochure>
  <m1-14-4-2-investigational-drug-label>
  </m1-14-4-2-investigational-drug-label>
  <m1-14-5-foreign-labeling>
  </m1-14-5-foreign-labeling>
</m1-14-4-investigational-drug-labeling>
</m1-14-labeling>
<m1-15-promotional-material>
</m1-15-promotional-material>
<m1-16-risk-management-plans>
</m1-16-risk-management-plans>
</m1-regional>
/fda-regional:fda-regional>
```

V. DOCUMENT TYPE DEFINITION (DTD)

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- ===== DTD INFORMATION ===== -->
<!-- US-regional DTD Version 2.01 -->
<!-- ===== TOP LEVEL ELEMENTS ===== -->
<!ENTITY % att " ID ID #IMPLIED
  xml:lang CDATA #IMPLIED">
<!ELEMENT fda-regional:fda-regional (admin, m1-regional?)>
<!ATTLIST fda-regional:fda-regional
  xmlns:fda-regional CDATA #FIXED "http://www.ich.org/fda"
  xmlns:xlink CDATA #FIXED "http://www.w3c.org/1999/xlink"
  xml:lang CDATA #IMPLIED
  dtd-version CDATA #FIXED "2.0"
>
<!-- ===== LEAF CONTENT ===== -->
<!ELEMENT leaf (title, link-text?)>
<!ATTLIST leaf
  ID ID #IMPLIED
  application-version CDATA #IMPLIED
  version CDATA #IMPLIED
  font-library CDATA #IMPLIED
  operation (new | append | replace | delete) #REQUIRED
  modified-file CDATA #IMPLIED
  checksum CDATA #IMPLIED
```

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```
checksum-type CDATA #IMPLIED
keywords CDATA #IMPLIED
xmlns:xlink CDATA #FIXED "http://www.w3c.org/1999/xlink"
xlink:type CDATA #FIXED "simple"
xlink:role CDATA #IMPLIED
xlink:href CDATA #IMPLIED
xlink:show (new | replace | embed | other | none) #IMPLIED
xlink:actuate (onLoad | onRequest | other | none) #IMPLIED
xml:lang CDATA #IMPLIED
>
<!ELEMENT title (#PCDATA)>
<!ATTLIST title
  ID ID #IMPLIED
>
<!ELEMENT link-text (#PCDATA | xref)*>
<!ATTLIST link-text
  ID ID #IMPLIED
>
<!ELEMENT xref EMPTY>
<!ATTLIST xref
  ID ID #IMPLIED
  xmlns:xlink CDATA #FIXED "http://www.w3c.org/1999/xlink"
  xlink:type CDATA #FIXED "simple"
  xlink:role CDATA #IMPLIED
  xlink:title CDATA #REQUIRED
  xlink:href CDATA #REQUIRED
  xlink:show (new | replace | embed | other | none) #IMPLIED
  xlink:actuate (onLoad | onRequest | other | none) #IMPLIED
>
<!ELEMENT node-extension (title, (leaf | node-extension)+)>
<!ATTLIST node-extension
  ID ID #IMPLIED
  xml:lang CDATA #IMPLIED
>
<!-- ===== ADMIN ===== -->
<!ELEMENT admin (applicant-info, product-description, application-information)>
<!-- ***** Applicant Information ***** -->
<!ELEMENT applicant-info (company-name, date-of-submission)>
<!ELEMENT company-name (#PCDATA)>
<!ELEMENT date-of-submission (date)>
<!ELEMENT date (#PCDATA)>
<!ATTLIST date
  format (yyyymmdd) #REQUIRED
>
<!-- ***** Product Description ***** -->
<!ELEMENT product-description (application-number, prod-name+)>
```

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```
<!ELEMENT application-number (#PCDATA)>
<!ELEMENT prod-name (#PCDATA)>
<!ATTLIST prod-name
  type (established | proprietary | chemical | code) #REQUIRED
>
<!-- ***** Application Information ***** -->
<!ELEMENT application-information (submission)>
<!ATTLIST application-information
  application-type (nda | anda | bla | dmf | ind | master-file) #REQUIRED
>
<!ELEMENT submission (sequence-number, related-sequence-number*)>
<!ATTLIST submission
  submission-type (
    original-application |
    amendment |
    resubmission |
    presubmission |
    annual-report |
    establishment-description-supplement |
    efficacy-supplement | labeling-supplement |
    chemistry-manufacturing-controls-supplement |
    other) #REQUIRED
>
<!ELEMENT sequence-number (#PCDATA)>
<!ELEMENT related-sequence-number (#PCDATA)>
<!-- ===== M1 REGIONAL STRUCTURE ===== -->
<!ELEMENT m1-regional (
  m1-1-forms?,
  m1-2-cover-letters?,
  m1-3-administrative-information?,
  m1-4-references?,
  m1-5-application-status?,
  m1-6-meetings?,
  m1-7-fast-track?,
  m1-8-special-protocol-assessment-request?,
  m1-9-pediatric-administrative-information?,
  m1-10-dispute-resolution?,
  m1-11-information-amendment?,
  m1-12-other-correspondence?,
  m1-13-annual-report?,
  m1-14-labeling?,
  m1-15-promotional-material?,
  m1-16-risk-management-plans?)>
<!ATTLIST m1-regional
  %att;
>
```

```
<!-- ===== FORMS ===== -->
<!ELEMENT m1-1-forms (
  m1-1-1-fda-form-1571 |
  m1-1-2-fda-form-356h |
  m1-1-3-fda-form-3397 |
  m1-1-4-fda-form-2252 |
  m1-1-5-fda-form-2253 |
  m1-1-6-fda-form-2567)>
<!ATTLIST m1-1-forms
  %att;
>
<!ELEMENT m1-1-1-fda-form-1571 ((leaf | node-extension)*)>
<!ATTLIST m1-1-1-fda-form-1571
  %att;
>
<!ELEMENT m1-1-2-fda-form-356h ((leaf | node-extension)*)>
<!ATTLIST m1-1-2-fda-form-356h
  %att;
>
<!ELEMENT m1-1-3-fda-form-3397 ((leaf | node-extension)*)>
<!ATTLIST m1-1-3-fda-form-3397
  %att;
>
<!ELEMENT m1-1-4-fda-form-2252 ((leaf | node-extension)*)>
<!ATTLIST m1-1-4-fda-form-2252
  %att;
>
<!ELEMENT m1-1-5-fda-form-2253 ((leaf | node-extension)*)>
<!ATTLIST m1-1-5-fda-form-2253
  %att;
>
<!ELEMENT m1-1-6-fda-form-2567 ((leaf | node-extension)*)>
<!ATTLIST m1-1-6-fda-form-2567
  %att;
>
<!-- ===== COVER LETTERS ===== -->
<!ELEMENT m1-2-cover-letters ((leaf | node-extension)*)>
<!ATTLIST m1-2-cover-letters
  %att;
>
<!-- ===== ADMINISTRATIVE INFORMATION ===== -->
<!ELEMENT m1-3-administrative-information (
  m1-3-1-applicant-information*,
  m1-3-2-field-copy-certification*,
  m1-3-3-debarment-certification*,
  m1-3-4-financial-certification-disclosure*,
```

```
    m1-3-5-patent-exclusivity*)>
<!ATTLIST m1-3-administrative-information
  %att;
>
<!ELEMENT m1-3-1-applicant-information (
  m1-3-1-1-change-of-address-or-corporate-name*,
  m1-3-1-2-change-contact-agent*,
  m1-3-1-3-change-in-sponsor*,
  m1-3-1-4-transfer-obligation*,
  m1-3-1-5-change-application-ownership*)>
<!ATTLIST m1-3-1-applicant-information
  %att;
>
<!ELEMENT m1-3-1-1-change-of-address-or-corporate-name
  ((leaf | node-extension)*)>
<!ATTLIST m1-3-1-1-change-of-address-or-corporate-name
  %att;
>
<!ELEMENT m1-3-1-2-change-contact-agent ((leaf | node-extension)*)>
<!ATTLIST m1-3-1-2-change-contact-agent
  %att;
>
<!ELEMENT m1-3-1-3-change-in-sponsor ((leaf | node-extension)*)>
<!ATTLIST m1-3-1-3-change-in-sponsor
  %att;
>
<!ELEMENT m1-3-1-4-transfer-obligation ((leaf | node-extension)*)>
<!ATTLIST m1-3-1-4-transfer-obligation
  %att;
>
<!ELEMENT m1-3-1-5-change-application-ownership ((leaf | node-extension)*)>
<!ATTLIST m1-3-1-5-change-application-ownership
  %att;
>
<!-- ===== FIELD COPY CERTIFICATION ===== -->
<!ELEMENT m1-3-2-field-copy-certification ((leaf | node-extension)*)>
<!ATTLIST m1-3-2-field-copy-certification
  %att;
>
<!-- ===== DEBARMENT CERTIFICATION ===== -->
<!ELEMENT m1-3-3-debarment-certification ((leaf | node-extension)*)>
<!ATTLIST m1-3-3-debarment-certification
  %att;
>
<!-- ===== FINANCIAL CERTIFICATION DISCLOSURE ===== -->
<!ELEMENT m1-3-4-financial-certification-disclosure ((leaf | node-extension)*)>
```

```
<!ATTLIST m1-3-4-financial-certification-disclosure
  %att;
>
<!-- ===== PATENT EXCLUSIVITY =====
-->
<!ELEMENT m1-3-5-patent-exclusivity (
  m1-3-5-1-patent-information*,
  m1-3-5-2-patent-certification*,
  m1-3-5-3-exclusivity-request*)>
<!ATTLIST m1-3-5-patent-exclusivity
  %att;
>
<!ELEMENT m1-3-5-1-patent-information ((leaf | node-extension)*)>
<!ATTLIST m1-3-5-1-patent-information
  %att;
>
<!ELEMENT m1-3-5-2-patent-certification ((leaf | node-extension)*)>
<!ATTLIST m1-3-5-2-patent-certification
  %att;
>
<!ELEMENT m1-3-5-3-exclusivity-request ((leaf | node-extension)*)>
<!ATTLIST m1-3-5-3-exclusivity-request
  %att;
>
<!-- ===== REFERENCES ===== -->
<!ELEMENT m1-4-references (
  m1-4-1-letter-authorization*,
  m1-4-2-statement-right-reference*,
  m1-4-3-list-of-authorized-persons-to-incorporate-by-reference*,
  m1-4-4-cross-reference-other-applications*)>
<!ATTLIST m1-4-references
  %att;
>
<!ELEMENT m1-4-1-letter-authorization ((leaf | node-extension)*)>
<!ATTLIST m1-4-1-letter-authorization
  %att;
>
<!ELEMENT m1-4-2-statement-right-reference ((leaf | node-extension)*)>
<!ATTLIST m1-4-2-statement-right-reference
  %att;
>
<!ELEMENT m1-4-3-list-of-authorized-persons-to-incorporate-by-reference
  ((leaf | node-extension)*)>
<!ATTLIST m1-4-3-list-of-authorized-persons-to-incorporate-by-reference
  %att;
>
```

```
<!ELEMENT m1-4-4-cross-reference-other-applications ((leaf | node-extension)*)>
<!ATTLIST m1-4-4-cross-reference-other-applications
  %att;
>
<!-- ===== APPLICATION STATUS ===== -->
<!ELEMENT m1-5-application-status (
  m1-5-1-withdrawal-request*,
  m1-5-2-inactivation-request*,
  m1-5-3-reactivation-request*,
  m1-5-4-reinstatement-request*,
  m1-5-5-withdrawal-unapproved-nda*,
  m1-5-6-withdrawal-of-listed-drug*,
  m1-5-7-request-withdrawal-application-approval*)>
<!ATTLIST m1-5-application-status
  %att;
>
<!ELEMENT m1-5-1-withdrawal-request ((leaf | node-extension)*)>
<!ATTLIST m1-5-1-withdrawal-request
  %att;
>
<!ELEMENT m1-5-2-inactivation-request ((leaf | node-extension)*)>
<!ATTLIST m1-5-2-inactivation-request
  %att;
>
<!ELEMENT m1-5-3-reactivation-request ((leaf | node-extension)*)>
<!ATTLIST m1-5-3-reactivation-request
  %att;
>
<!ELEMENT m1-5-4-reinstatement-request ((leaf | node-extension)*)>
<!ATTLIST m1-5-4-reinstatement-request
  %att;
>
<!ELEMENT m1-5-5-withdrawal-unapproved-nda ((leaf | node-extension)*)>
<!ATTLIST m1-5-5-withdrawal-unapproved-nda
  %att;
>
<!ELEMENT m1-5-6-withdrawal-of-listed-drug ((leaf | node-extension)*)>
<!ATTLIST m1-5-6-withdrawal-of-listed-drug
  %att;
>
<!ELEMENT m1-5-7-request-withdrawal-application-approval ((leaf | node-extension)*)>
<!ATTLIST m1-5-7-request-withdrawal-application-approval
  %att;
>
<!-- ===== MEETINGS ===== -->
```

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```
<!ELEMENT m1-6-meetings (m1-6-1-meeting-request*, m1-6-2-meeting-background-
materials*, m1-6-3-correspondence-regarding-meetings*)>
<!ATTLIST m1-6-meetings
  %att;
>
<!ELEMENT m1-6-1-meeting-request ((leaf | node-extension)*)>
<!ATTLIST m1-6-1-meeting-request
  %att;
>
<!ELEMENT m1-6-2-meeting-background-materials ((leaf | node-extension)*)>
<!ATTLIST m1-6-2-meeting-background-materials
  %att;
>
<!ELEMENT m1-6-3-correspondence-regarding-meetings ((leaf | node-extension)*)>
<!ATTLIST m1-6-3-correspondence-regarding-meetings
  %att;
>
<!-- ===== FAST TRACK ===== -->
<!ELEMENT m1-7-fast-track (
  m1-7-1-fast-track-designation-request*,
  m1-7-2-fast-track-designation-withdrawal-request*,
  m1-7-3-rolling-review-request*)>
<!ATTLIST m1-7-fast-track
  %att;
>
<!ELEMENT m1-7-1-fast-track-designation-request ((leaf | node-extension)*)>
<!ATTLIST m1-7-1-fast-track-designation-request
  %att;
>
<!ELEMENT m1-7-2-fast-track-designation-withdrawal-request
  ((leaf | node-extension)*)>
<!ATTLIST m1-7-2-fast-track-designation-withdrawal-request
  %att;
>
<!ELEMENT m1-7-3-rolling-review-request ((leaf | node-extension)*)>
<!ATTLIST m1-7-3-rolling-review-request
  %att;
>
<!-- ===== SPECIAL PROTOCOL ASSESSMENT REQUEST ===== -->
<!ELEMENT m1-8-special-protocol-assessment-request (
  m1-8-1-clinical-study*,
  m1-8-2-carcinogenicity-study*,
  m1-8-3-stability-study*)>
<!ATTLIST m1-8-special-protocol-assessment-request
  %att;
>
```

```
<!ELEMENT m1-8-1-clinical-study ((leaf | node-extension)*)>
<!ATTLIST m1-8-1-clinical-study
  %att;
>
<!ELEMENT m1-8-2-carcinogenicity-study ((leaf | node-extension)*)>
<!ATTLIST m1-8-2-carcinogenicity-study
  %att;
>
<!ELEMENT m1-8-3-stability-study ((leaf | node-extension)*)>
<!ATTLIST m1-8-3-stability-study
  %att;
>
<!-- ===== PEDIATRIC ADMINISTRATIVE INFORMATION ===== -->
<!ELEMENT m1-9-pediatric-administrative-information (
  m1-9-1-request-waiver-pediatric-studies*,
  m1-9-2-request-deferral-pediatric-studies*,
  m1-9-3-request-pediatric-exclusivity-determination*,
  m1-9-4-proposed-pediatric-study-request-amendments*,
  m1-9-5-proposal-written-agreement*,
  m1-9-6-other-correspondence-regarding-pediatric-exclusivity-study-plans*)>
<!ATTLIST m1-9-pediatric-administrative-information
  %att;
>
<!ELEMENT m1-9-1-request-waiver-pediatric-studies ((leaf | node-extension)*)>
<!ATTLIST m1-9-1-request-waiver-pediatric-studies
  %att;
>
<!ELEMENT m1-9-2-request-deferral-pediatric-studies ((leaf | node-extension)*)>
<!ATTLIST m1-9-2-request-deferral-pediatric-studies
  %att;
>
<!ELEMENT m1-9-3-request-pediatric-exclusivity-determination
  ((leaf | node-extension)*)>
<!ATTLIST m1-9-3-request-pediatric-exclusivity-determination
  %att;
>
<!ELEMENT m1-9-4-proposed-pediatric-study-request-amendments
  ((leaf | node-extension)*)>
<!ATTLIST m1-9-4-proposed-pediatric-study-request-amendments
  %att;
>
<!ELEMENT m1-9-5-proposal-written-agreement ((leaf | node-extension)*)>
<!ATTLIST m1-9-5-proposal-written-agreement
  %att;
>
<!ELEMENT m1-9-6-other-correspondence-regarding-pediatric-exclusivity-study-plans
```

```
((leaf | node-extension)*>
<!ATTLIST m1-9-6-other-correspondence-regarding-pediatric-exclusivity-study-plans
  %att;
>
<!-- ===== DISPUTE RESOLUTION ===== -->
<!ELEMENT m1-10-dispute-resolution (
  m1-10-1-request-for-dispute-resolution*,
  m1-10-2-correspondence-related-to-dispute-resolution*)>
<!ATTLIST m1-10-dispute-resolution
  %att;
>
<!ELEMENT m1-10-1-request-for-dispute-resolution ((leaf | node-extension)*>
<!ATTLIST m1-10-1-request-for-dispute-resolution
  %att;
>
<!ELEMENT m1-10-2-correspondence-related-to-dispute-resolution ((leaf | node-
extension)*>
<!ATTLIST m1-10-2-correspondence-related-to-dispute-resolution
  %att;
>
<!-- ===== INFORMATION ADMENDMENT ===== -->
<!ELEMENT m1-11-information-amendment (
  m1-11-1-quality-information-amendment*,
  m1-11-2-safety-information-amendment*,
  m1-11-3-efficacy-information-amendment*,
  m1-11-4-multiple-module-information-amendments*)>
<!ATTLIST m1-11-information-amendment
  %att;
>
<!ELEMENT m1-11-1-quality-information-amendment ((leaf | node-extension)*>
<!ATTLIST m1-11-1-quality-information-amendment
  %att;
>
<!ELEMENT m1-11-2-safety-information-amendment ((leaf | node-extension)*>
<!ATTLIST m1-11-2-safety-information-amendment
  %att;
>
<!ELEMENT m1-11-3-efficacy-information-amendment ((leaf | node-extension)*>
<!ATTLIST m1-11-3-efficacy-information-amendment
  %att;
>
<!ELEMENT m1-11-4-multiple-module-information-amendments
  ((leaf | node-extension)*>
<!ATTLIST m1-11-4-multiple-module-information-amendments
  %att;
>
```

```
<!-- ===== OTHER CORRESPONDENCE ===== -->
<!ELEMENT m1-12-other-correspondence (
  m1-12-1-pre-ind-correspondence*,
  m1-12-2-request-charge*,
  m1-12-3-notification-charging-under-treatment-ind*,
  m1-12-4-request-comments-advice-ind*,
  m1-12-5-request-waiver*,
  m1-12-6-exemption-informed-consent-emergency-research*,
  m1-12-7-public-disclosure-statement-emergency-care-research*,
  m1-12-8-correspondence-regarding-emergency-care-research*,
  m1-12-9-notification-discontinuation-clinical-trial*,
  m1-12-10-generic-drug-enforcement-act-statement*,
  m1-12-11-basis-submission-statement*,
  m1-12-12-comparison-generic-drug-reference-listed-drug*,
  m1-12-13-request-waiver-in-vivo-studies*,
  m1-12-14-environmental-analysis*,
  m1-12-15-request-waiver-in-vivo-bioavailability-studies*,
  m1-12-16-field-alert-reports*)>
<!ATTLIST m1-12-other-correspondence
  %att;
>
<!ELEMENT m1-12-1-pre-ind-correspondence ((leaf | node-extension)*)>
<!ATTLIST m1-12-1-pre-ind-correspondence
  %att;
>
<!ELEMENT m1-12-2-request-charge ((leaf | node-extension)*)>
<!ATTLIST m1-12-2-request-charge
  %att;
>
<!ELEMENT m1-12-3-notification-charging-under-treatment-ind
  ((leaf | node-extension)*)>
<!ATTLIST m1-12-3-notification-charging-under-treatment-ind
  %att;
>
<!ELEMENT m1-12-4-request-comments-advice-ind ((leaf | node-extension)*)>
<!ATTLIST m1-12-4-request-comments-advice-ind
  %att;
>
<!ELEMENT m1-12-5-request-waiver ((leaf | node-extension)*)>
<!ATTLIST m1-12-5-request-waiver
  %att;
>
<!ELEMENT m1-12-6-exemption-informed-consent-emergency-research
  ((leaf | node-extension)*)>
<!ATTLIST m1-12-6-exemption-informed-consent-emergency-research
  %att;
```

```
>
<!ELEMENT m1-12-7-public-disclosure-statement-emergency-care-research
  ((leaf | node-extension)*)>
<!ATTLIST m1-12-7-public-disclosure-statement-emergency-care-research
  %att;
>
<!ELEMENT m1-12-8-correspondence-regarding-emergency-care-research
  ((leaf | node-extension)*)>
<!ATTLIST m1-12-8-correspondence-regarding-emergency-care-research
  %att;
>
<!ELEMENT m1-12-9-notification-discontinuation-clinical-trial ((leaf | node-extension)*)>
<!ATTLIST m1-12-9-notification-discontinuation-clinical-trial
  %att;
>
<!ELEMENT m1-12-10-generic-drug-enforcement-act-statement
  ((leaf | node-extension)*)>
<!ATTLIST m1-12-10-generic-drug-enforcement-act-statement
  %att;
>
<!ELEMENT m1-12-11-basis-submission-statement ((leaf | node-extension)*)>
<!ATTLIST m1-12-11-basis-submission-statement
  %att;
>
<!ELEMENT m1-12-12-comparison-generic-drug-reference-listed-drug
  ((leaf | node-extension)*)>
<!ATTLIST m1-12-12-comparison-generic-drug-reference-listed-drug
  %att;
>
<!ELEMENT m1-12-13-request-waiver-in-vivo-studies ((leaf | node-extension)*)>
<!ATTLIST m1-12-13-request-waiver-in-vivo-studies
  %att;
>
<!ELEMENT m1-12-14-environmental-analysis ((leaf | node-extension)*)>
<!ATTLIST m1-12-14-environmental-analysis
  %att;
>
<!ELEMENT m1-12-15-request-waiver-in-vivo-bioavailability-studies
  ((leaf | node-extension)*)>
<!ATTLIST m1-12-15-request-waiver-in-vivo-bioavailability-studies
  %att;
>
<!ELEMENT m1-12-16-field-alert-reports ((leaf | node-extension)*)>
<!ATTLIST m1-12-16-field-alert-reports
  %att;
>
```

```
<!-- ===== ANNUAL REPORT ===== -->
<!ELEMENT m1-13-annual-report (
  m1-13-1-summary-nonclinical-studies*,
  m1-13-2-summary-clinical-pharmacology-information*,
  m1-13-3-summary-safety-information*,
  m1-13-4-summary-labeling-changes*,
  m1-13-5-summary-manufacturing-changes*,
  m1-13-6-summary-microbiological-changes*,
  m1-13-7-summary-other-significant-new-information*,
  m1-13-8-individual-study-information*,
  m1-13-9-general-investigational-plan*,
  m1-13-10-foreign-marketing-history*,
  m1-13-11-distribution-data*,
  m1-13-12-status-postmarketing-study-commitments*,
  m1-13-13-status-other-postmarketing-studies*,
  m1-13-14-log-outstanding-regulatory-business*)>
<!ATTLIST m1-13-annual-report
  %att;
>
<!ELEMENT m1-13-1-summary-nonclinical-studies ((leaf | node-extension)*)>
<!ATTLIST m1-13-1-summary-nonclinical-studies
  %att;
>
<!ELEMENT m1-13-2-summary-clinical-pharmacology-information
  ((leaf | node-extension)*)>
<!ATTLIST m1-13-2-summary-clinical-pharmacology-information
  %att;
>
<!ELEMENT m1-13-3-summary-safety-information ((leaf | node-extension)*)>
<!ATTLIST m1-13-3-summary-safety-information
  %att;
>
<!ELEMENT m1-13-4-summary-labeling-changes ((leaf | node-extension)*)>
<!ATTLIST m1-13-4-summary-labeling-changes
  %att;
>
<!ELEMENT m1-13-5-summary-manufacturing-changes ((leaf | node-extension)*)>
<!ATTLIST m1-13-5-summary-manufacturing-changes
  %att;
>
<!ELEMENT m1-13-6-summary-microbiological-changes ((leaf | node-extension)*)>
<!ATTLIST m1-13-6-summary-microbiological-changes
  %att;
>
<!ELEMENT m1-13-7-summary-other-significant-new-information
  ((leaf | node-extension)*)>
```

```
<!ATTLIST m1-13-7-summary-other-significant-new-information
  %att;
>
<!ELEMENT m1-13-8-individual-study-information ((leaf | node-extension)*)>
<!ATTLIST m1-13-8-individual-study-information
  %att;
>
<!ELEMENT m1-13-9-general-investigational-plan ((leaf | node-extension)*)>
<!ATTLIST m1-13-9-general-investigational-plan
  %att;
>
<!ELEMENT m1-13-10-foreign-marketing-history ((leaf | node-extension)*)>
<!ATTLIST m1-13-10-foreign-marketing-history
  %att;
>
<!ELEMENT m1-13-11-distribution-data ((leaf | node-extension)*)>
<!ATTLIST m1-13-11-distribution-data
  %att;
>
<!ELEMENT m1-13-12-status-postmarketing-study-commitments
  ((leaf | node-extension)*)>
<!ATTLIST m1-13-12-status-postmarketing-study-commitments
  %att;
>
<!ELEMENT m1-13-13-status-other-postmarketing-studies ((leaf | node-extension)*)>
<!ATTLIST m1-13-13-status-other-postmarketing-studies
  %att;
>
<!ELEMENT m1-13-14-log-outstanding-regulatory-business ((leaf | node-extension)*)>
<!ATTLIST m1-13-14-log-outstanding-regulatory-business
  %att;
>
<!-- ===== LABELING =====
-->
<!ELEMENT m1-14-labeling (
  m1-14-1-draft-labeling*,
  m1-14-2-final-labeling*,
  m1-14-3-listed-drug-labeling*,
  m1-14-4-investigational-drug-labeling*,
  m1-14-5-foreign-labeling*)>
<!ATTLIST m1-14-labeling
  %att;
>
<!ELEMENT m1-14-1-draft-labeling (
  m1-14-1-1-draft-carton-container-labels*,
  m1-14-1-2-annotated-draft-labeling-text*,
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```
    m1-14-1-3-draft-labeling-text*,
    m1-14-1-4-label-comprehension-studies*,
    m1-14-1-5-labeling-history*)>
<!ATTLIST m1-14-1-draft-labeling
  %att;
>
<!ELEMENT m1-14-1-1-draft-carton-container-labels ((leaf | node-extension)*)>
<!ATTLIST m1-14-1-1-draft-carton-container-labels
  %att;
>
<!ELEMENT m1-14-1-2-annotated-draft-labeling-text ((leaf | node-extension)*)>
<!ATTLIST m1-14-1-2-annotated-draft-labeling-text
  %att;
>
<!ELEMENT m1-14-1-3-draft-labeling-text ((leaf | node-extension)*)>
<!ATTLIST m1-14-1-3-draft-labeling-text
  %att;
>
<!ELEMENT m1-14-1-4-label-comprehension-studies ((leaf | node-extension)*)>
<!ATTLIST m1-14-1-4-label-comprehension-studies
  %att;
>
<!ELEMENT m1-14-1-5-labeling-history ((leaf | node-extension)*)>
<!ATTLIST m1-14-1-5-labeling-history
  %att;
>
<!ELEMENT m1-14-2-final-labeling (
  m1-14-2-1-final-carton-container-labels*,
  m1-14-2-2-final-package-insert-package-inserts*,
  m1-14-2-3-final-labeling-text*)>
<!ATTLIST m1-14-2-final-labeling
  %att;
>
<!ELEMENT m1-14-2-1-final-carton-container-labels ((leaf | node-extension)*)>
<!ATTLIST m1-14-2-1-final-carton-container-labels
  %att;
>
<!ELEMENT m1-14-2-2-final-package-insert-package-inserts ((leaf | node-extension)*)>
<!ATTLIST m1-14-2-2-final-package-insert-package-inserts
  %att;
>
<!ELEMENT m1-14-2-3-final-labeling-text ((leaf | node-extension)*)>
<!ATTLIST m1-14-2-3-final-labeling-text
  %att;
>
<!ELEMENT m1-14-3-listed-drug-labeling (
```

```
    m1-14-3-1-annotated-comparison-listed-drug*,
    m1-14-3-2-approved-labeling-text-listed-drug*,
    m1-14-3-3-labeling-text-reference-listed-drug*)>
<!ATTLIST m1-14-3-listed-drug-labeling
  %att;
>
<!ELEMENT m1-14-3-1-annotated-comparison-listed-drug ((leaf | node-extension)*)>
<!ATTLIST m1-14-3-1-annotated-comparison-listed-drug
  %att;
>
<!ELEMENT m1-14-3-2-approved-labeling-text-listed-drug ((leaf | node-extension)*)>
<!ATTLIST m1-14-3-2-approved-labeling-text-listed-drug
  %att;
>
<!ELEMENT m1-14-3-3-labeling-text-reference-listed-drug ((leaf | node-extension)*)>
<!ATTLIST m1-14-3-3-labeling-text-reference-listed-drug
  %att;
>
<!ELEMENT m1-14-4-investigational-drug-labeling (
  m1-14-4-1-investigational-brochure*,
  m1-14-4-2-investigational-drug-label*)>
<!ATTLIST m1-14-4-investigational-drug-labeling
  %att;
>
<!ELEMENT m1-14-4-1-investigational-brochure ((leaf | node-extension)*)>
<!ATTLIST m1-14-4-1-investigational-brochure
  %att;
>
<!ELEMENT m1-14-4-2-investigational-drug-label ((leaf | node-extension)*)>
<!ATTLIST m1-14-4-2-investigational-drug-label
  %att;
>
<!ELEMENT m1-14-5-foreign-labeling ((leaf | node-extension)*)>
<!ATTLIST m1-14-5-foreign-labeling
  %att;
>
<!-- ===== PROMOTIONAL MATERIAL ===== -->
<!ELEMENT m1-15-promotional-material ((leaf | node-extension)*)>
<!ATTLIST m1-15-promotional-material
  %att;
>
<!-- ===== RISK MANAGEMENT ===== -->
<!ELEMENT m1-16-risk-management-plans ((leaf | node-extension)*)>
<!ATTLIST m1-16-risk-management-plans
  %att;
>
```

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